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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/502,283 02/11/00 RAILLARD

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LAW OFFICES OF JONATHAN ALAN QUINE
P O BOX 458
ALAMEDA CA 94501

EXAMINER

BRASHTON, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/502,283

Applicant(s)

RAILLARD ET AL.

Examiner

Thomas W Prasthofer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2001 and 12 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

Detailed Action
Status of the Application

Receipt is acknowledged of a request for corrected filing receipt on August 2, 2000 (Paper No. 8) and an information disclosure statement on August 12, 2000 (Paper No. 7).

Status of the Claims

Claims 1-71 are pending in the present application and are subject to restriction and election of species requirements.

Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26, drawn to a method of performing high throughput mass spectrometry, classified in class 250, subclass 288.
 - II. Claims 27-43, drawn to a method for monitoring one or more products or reactants by high throughput mass spectrometry, classified in class 435, subclass 70.
 - III. Claims 44-63, drawn to an apparatus for high throughput mass spectrometry screening, classified in class 435, subclass 287.3.
 - IV. Claims 64-71, drawn to a method of analyzing a plurality of components, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and IV are different and patentably distinct methods that include different method steps, require different reagents and conditions, and produce different results. For

example, Invention II includes the step of producing products or reactants in a biological matrix that is not present in Inventions I or IV. Inventions I and II involve the use of cells while Invention IV does not. Invention IV uses tags and solid supports while Inventions I and II do not. The method of Invention I can be performed using only one cell and obtains mass to charge ratios while Invention II requires more than one cell and does not require obtaining mass to charge ratios and Invention IV does not require cells or mass spectrometry.

Inventions (I or II) and Invention III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of Invention III can be used to practice either of Inventions I or II and Inventions I and II can be practiced manually in combination with a mass spectrometer as an alternative to using the apparatus of Invention III.

Inventions III and IV are different and patentably distinct inventions because Invention III is an apparatus that is not used in the method of Invention IV.

Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

2. This application contains claims directed to patentably distinct species of the claimed invention. If applicant elects Invention I, applicant is required to elect a patentably distinct species for each of the following categories:

A) Species of (method of) purifying one or more non-column-separated components from one or more cells,

B) Species of non-column-separated component (if applicant elects enzymes, elect specific enzyme),

- C) Species of activity of the one or more non-column-separated components,
- D) Species of environment in which step (ii) of claim 1 is performed (i.e. a volatile buffer, a buffer that reduces concentration of ionic species, an ion exchange resin, or an organic solvent; see claim 12), AND
- E) Species from which components are produced (i.e. whole cell, cell lysate, cell supernatant, reactions of purified enzymes with added substrates; see claim 13).

A total of five species must be elected, one from each of A-E.

The species are distinct, each from the other, because they have different chemical, physical, and/or biological properties or they are different activities requiring different means of detection involving different reagents and conditions. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

If applicant elects Invention II, applicant is required to elect a patentably distinct species for each of the following categories:

- A) Species of related gene sequences,
 - B) Species of one or more products or reactants in the non-column-separated sample,
- AND
- C) Species of (method of) purifying the non-column-separated sample from the biological matrix,

A total of three species must be elected, one from each of A-E.

The species are distinct, each from the other, because they have different chemical, physical, and/or biological properties or they are different activities requiring different means of detection involving different reagents and conditions. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

If applicant elects Invention III, applicant is required to elect a patentably distinct species for each of the following categories:

- A) Species of cell growth plate,
- B) Species of reactants (i.e. enzyme, enzyme substrate, enzyme product),
- C) Species of off-line parallel purification system, AND
- D) Species of sample.

A total of four species must be elected, one from each of A-E.

The species are distinct, each from the other, because they have different chemical, physical, and/or biological properties or they are different activities requiring different means of detection involving different reagents and conditions. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

If applicant elects Invention IV, applicant is required to elect a patentably distinct species for each of the following categories:

- A) Species of component,
- B) Species of tag,
- C) Species of product, AND
- D) Species of analyzing.

A total of four species must be elected, one from each of A-E.

The species are distinct, each from the other, because they have different chemical, physical, and/or biological properties or they are different activities requiring different means of detection involving different reagents and conditions. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

3. Applicant is required under U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally to be allowable.

4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected species.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

Thomas Prasthofer, Ph.D

June 27, 2001

BENNETT CELSA
PRIMARY EXAMINER

